REMARKS

The present application includes claims 49-51 and 59-111. Claims 32-48 and 52-58 were cancelled and replaced by new claims 59-111. Claims 49-51 were amended. Applicants thank the Examiner for the interview of July 11, 2005.

Support

Claims 59 and 84 find support at least on page 11, paragraph 22:

"In some embodiments, the valve will be chosen and designed so that it responds only upon certain conditions occurring within the heart, such as the following: absolute left atrial pressure, differential atrial pressure, other intra-cardiac pressures, other cardiovascular pressures, or other physiological conditions that might correlate to an exacerbated state of diastolic heart failure, such as blood oxygen saturation or pH."

on page 13, paragraph 24:

"Unlike the LVAD, however, the disclosed invention does not seek to significantly "support" the function of the left ventricle by pumping blood from the LV chamber to the body. Rather, it is intended only to "offload" the excessive pressure that builds through the diastolic phase of the cardiac cycle in some CBF patients. Whereas a normal LVEDP is in the range of 6-12 mmHg, patients with diastolic dysfunction heart failure (DDHF), end-diastolic pressure (EDP) in the left atrium (LA) and left ventricle (LV) can rise considerably above normal levels."

in paragraph 27:

"in the event of an activation of the implanted device that corresponds to the significantly exacerbated state heart failure."

on page 16, paragraph 34:

"Thus for example, a chronic device can be a preventive device where when pressures rise for some reason to dangerous levels the pump goes into action and helps to lower the pressure in the left ventricle, thereby preventing the acute development of dyspnea and pulmonary edema and assures that the LVDP are always at an optimal level of no more than 15 mmHg."

and in the mention of mean LAP – mean RAP in paragraph 32.

Claim 60 finds support at least in paragraph 35 and in the passage "continuously moves a small amount of blood from the LV chamber to the aorta", in paragraph 23. Claim 61 finds support at least in paragraph 25. Claim 62 finds support at least in paragraph 26. Claim 63 finds support at least in paragraphs 28 and 29.

Claim 64 finds support at least in the end of paragraph 12:

"For example in patients presenting with diastolic heart failure (DHF) the present invention prevents this occurrence by reducing diastolic pressures in the left atrium below the excessive levels that would otherwise have caused pulmonary edema."

Claim 65 finds support at least in paragraph 22. Claim 66 finds support at least in paragraph 12. Claim 67 finds support at least in element 120 of Fig. 1, and paragraph 18. Claim 68 finds support at least in paragraph 18. Claim 69 finds support at least in paragraph 12: "a shunt-type device allows a small volume of blood to be released from the left ventricle to reduce the pressure.", as contrasts with paragraph 10: "The mechanical devices were built to allow propulsion of significant amount of blood (liters/min) and this is also their main technological limitation. The need for power supply, relatively large pumps and danger of hemolysis and infection are all of significant concern."

Claim 70 finds support at least in Figs. 1 and 5. Claims 71 and 72 find support at least in paragraph 32. Claim 73 finds support at least in paragraph 22. Claim 74 finds support at least in paragraph 33. Claim 75 finds support at least in paragraph 28. Claims 76-78 find support at least in Fig. 1. Claim 79 finds support at least in paragraph 19. Claim 80 finds support at least in pump 140 mentioned for example in paragraph 23. Claims 81-83 find support at least in paragraph 27.

Claims 85-86 and 89 find support at least in paragraph 36. Claims 87 and 88 find support at least in paragraph 24. Claim 90 finds support at least in paragraph 23. Claim 91 finds support at least in paragraph 27. Claims 92 and 98 find support at least in paragraph 22. Claims 93-97 finds support at least in paragraph 26. Claim 99 find support at least in paragraph 33. Claim 100 finds support at least in the mention of mean LAP – mean RAP in paragraph 32. Claim 101 finds support at least in paragraph 16.

Claims 102 and 111 find support at least in paragraph 37. Claim 103 finds support at least in paragraph 26. Claim 104 finds support throughout the application in examples of measurement of absolute pressure. Claims 105 and 106 find support at least in paragraph 30. Claims 107 and 108 find support at least in paragraphs 34 and paragraph 7, respectively. Claims 109 and 110 find support at least in paragraph 26.

The amendment to claim 51 finds support at least in paragraph 33.

Discussion

The Drawings and claims 35 and 50 were rejected for lack of description and support. Applicant cancelled these claims and replaced them by claim 78, which is reworded to avoid the Examiner's rejection.

The old claims were rejected under 35 USC 102 or 103(a) in view of US patent 6,458,153 to Bailey et al., and/or US patent 5,429,144 to Wilk and for some of the claims one or more additional reference.

New independent claim 59 overcomes these rejections in requiring a valve adapted to open only when a pressure level between opposite ends of the valve is above a threshold pressure greater than a highest pressure level between the left atria and the right atria of a normal heart.

In contrast, Wilk and Bailey relate to valves that open under normal pressures of systole and diastole (Bailey, col. 10, lines 37-39 and Wilk, col. 3, lines 61-63 and col. 10, lines 12-13).

Similarly, new independent claim 84 requires implanting a valve that opens responsive to a pressure level of an exacerbated state of heart failure but not under normal pressures of systole and diastole of a normal heart. This is not taught or suggested by the art of record.

The dependent claims are allowable at least because they depend on an allowable claim. Nonetheless, at least some of the dependent claims add further patentability over the art. Claim 68, for example, requires a tube with a diameter of less than 5 millimeters. In contrast, Bailey, mentions a 20+ French size (col. 3, line 23), which is 6.66 = 20/3+ millimeters.

Claim 60, for example, requires that the valve allows passage of blood therethrough throughout the cardiac cycle. In contrast, Bailey and Wilk only allow flow during a portion of the cardiac cycle.

New independent claim 103 requires a valve for operation within the heart whose opening is controlled at least partially responsive to readings of a sensor. Applicants did not find any teaching or suggestion of this in Bailey or Wilk.

In view of the above remarks, applicants submit that the claims are patentable over the prior art. Allowance of the application is respectfully awaited. If, however, the Examiner is not convinced and the Examiner is of the opinion that a telephone conversation may forward the present application toward allowance, applicants respectfully request that the Examiner call the undersigned at 1 (877) 428-5468. Please note that this is a direct *toll free* number in the US that is answered in the undersigned's Israel office. Israel is 7 hours ahead of Washington.

Respectfully submitted,
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